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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/579,357	05/16/2006	Reinhard Bolli	06478.1507	2138

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EXAMINER	
KIM, YUNSOO	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/579,357	BOLLI ET AL.	
	Examiner	Art Unit	
	YUNSOO KIM	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *18-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 May 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-23 are pending.

2. Applicants' election of Group I with traverse, claims 1-17 and 23 drawn to a stable protein preparation filed on 6/12/08 is acknowledged.

The traversal is on the grounds that the WO 98/28007 publication does not teach the preparation comprising a protein and one or more stabilizer(s) and the pH of the preparation is 4.2 to 5.4 as required by claim 1. This is not found persuasive because the prior art as represented by WO 98/28007 discloses an interferon (e.g. protein) composition comprising arginine or glycine and the pH of the preparation is 5 (claims 1-5, in particular). Given that claim 2 which further limits non-polar basic amino acids to histidine, arginine, lysine, ornithine, isoleucine, valine, methionine, glycine and proline, and the '007 publication specifically teaches the use of glycine or arginine, a single general inventive concept does not exist. Therefore, under PCT Rule 13.1 and 13.2, unity of invention does not exist. The requirement is still deemed proper and is therefore made FINAL.

Accordingly, as the invention in claims 1-23 do not relate to a single general inventive concept under PCT Rule 13.1, claims 18-22 are withdrawn from further consideration by the examiner 37 CFR 1.142 (b) as being drawn to a nonelected invention. Therefore claims 1-17 and 23 are currently being examined.

3. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been placed of record in the file.

4. Applicants' IDS filed on 5/16/06 has been acknowledged. However, the non-English foreign documents (Nos. 6 and 7) have not been considered and crossed out. Applicant is required to provide an English translation for consideration.

5. Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c). The oath filed on 8/16/06 contains non-initialed/non-dated alterations.

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1, 2, 5-8, 10, 12 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by WO98/28007 (IDS reference).

The '007 publication teaches an interferon-β formulation comprising glycine and/or arginine at pH 5.0 (claims 1-6) in stabilizing buffer (e.g. pharmaceutically acceptable additive). The '007 publication further teaches that the concentration of interferon-β is preferably 60ug/ml or (30ug/ml to 250ug/ml, or 3% to 25% (p. 12)) and the preparation is suitable for subcutaneous and the intravenous administrations (p.6). The concentration of 60ug/ml is equivalent to 6% w/v.

Given that the '007 publication further teaches the concentration of glycine is 70mM and arginine is 150mM (p. 3), the addition of concentrations equals to 0.22M and the claimed invention allows one or more stabilizers, claims 7-8 reciting 0.2M of one or more stabilizer(s) are included in this rejection. Therefore, the reference teachings anticipate the claimed invention.

8. Claims 1-4, 7-10, 12, 14-17 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Pat. No. 5,831,736 (IDS reference) as is evidenced by the specification on p.4 of the instant application.

The '736 patent teaches IgG formulation for intravenous administration at 3-16% w/v (preferably 6-12% w/v) concentration of IgG and a naturally occurring amino acid proline at pH range 5-6 and at 5.3 (col. 2-3, overlapping paragraph, col. 4, lines 55-60, Example 1, claims 1-14). As is evidenced by the specification of instant application on p. 4 that all naturally occurring amino acid is L-amino acid and the '736 patent discloses naturally occurring proline, claim 4 is included in this rejection.

The '736 patent further teaches the proline concentration is 200mM (0.2M, Table 2, col. 6) and addition of other amino acid such as glycine at concentration of 50mM. Given that the claimed

invention requires addition of one or more stabilizers and the concentration is additive, claim 9 is included in this rejection.

Moreover, the '736 patent teaches dosage of 0.2-1.0g of IgG per Kg body weight per day (col. 6, lines 1-3). Therefore, the reference teachings anticipate the claimed invention.

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 10-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO98/28007 (IDS reference).

The '007 publication has been discussed, supra.

The referenced concentration range of 3-25% w/v includes the claimed 15-20% w/v and 8-12% w/v. As the general conditions of the claims are disclosed in the reference, it is not inventive to discover the optimum or workable ranges by routine examination (MPEP 2144.05). Therefore, the claimed preparation is included in the formulation taught by the reference in the absence of showing any unobvious differences.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by reference, especially in the absence to the contrary.

11. Claims 1, 5, 6, 10, 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,831,736 (IDS reference).

The '736 patent has been discussed, supra.

The referenced concentration range of 3-16% w/v includes the claimed 8-12% w/v and the referenced preferable pH of 4-8, preferably 5-6 and most preferably 5.2 to 5.4 includes the claimed pH of 4.6 to 5.0. As the general conditions of the claims are disclosed in the reference, it is not inventive to discover the optimum or workable ranges by routine examination (MPEP 2144.05). Therefore, the claimed preparation is included in the formulation taught by the reference in the absence of showing any unobvious differences.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by reference, especially in the absence to the contrary.

12. Claims 1, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,831,736 (IDS reference) in view of U.S. Pat. No. 6,252, 055.

The teachings of the '736 patent have been discussed, supra.

The '736 patent does not teach subcutaneous administration with concentration of 15-20% of protein as in claim 11.

However, the '055 patent teaches administration of IgG subcutaneously at the concentration of 150-200mg/ml (equivalent to 15-20% w/v). The '055 patent further teaches that the subcutaneous administration has an advantage as it can be self administered and avoid the need of hospitalization for intravenous administration (col. 4, lines 11-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer IgG formulation taught by the '736 patent subcutaneously as taught by the '055 patent.

The ordinary skill in the art would have been motivated to combine the teachings of the '736 patent and the '055 patent because the subcutaneous administration has the advantage over intravenous administration as the subcutaneous administration can be self administered and avoids hospitalization.

From the teachings of the references, it would have been obvious to one of ordinary skill in the art to combine the teachings of the references and there would have been a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

13. No claims are allowable.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yunsoo Kim whose telephone number is 571-272-3176. The examiner can normally be reached on M-F,9-5.If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen B. O'Hara can be reached on 571-272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Yunsoo Kim
Patent Examiner
Technology Center 1600
September 18, 2008

/Yunsoo Kim/

Patent Examiner, Art Unit 1644